EPA REGION 8 QA DOCUMENT REVIEW CROSSWALK

QAPP/FSP/SAP for: *(check appropriate box)*	**Entity** *(grantee, contract, EPA AO, EPA Program, Other)*	**Regulatory Authority**	___**40 CFR 31 for Grants**
___ **GRANTEE**	Columbia Falls Aluminum Company, LLC (Glencore)		___**48 CFR Part 46 for Contracts**
___ **CONTRACTOR**		**and/or**	___ **Interagency Agreement**
___ **EPA**			___ **EPA Administrative Order**
___ **Other**		**Funding Mechanism**	___ **EPA Program Funding**
			___ **EPA Program Regulation**
			___ **EPA CIO 2105**
Document Title *[Note: Title will be repeated in Header]*	Draft Phase 1 Site Characterization Sampling and Analysis Plan, Remedial Investigation/Feasibility Study Work Plan, Former Primary Aluminum Reduction Facility, Columbia Falls, Montana (June 5, 2015)		
QAPP/FSP/SAP Preparer	Roux Associates, Inc.		
Period of Performance *(of QAPP/FSP/SAP)*		**Date Submitted for Review**	
EPA Project Officer **EPA Project Manager**	Mike Cirian (EPA)	**PO Phone #** **PM Phone #**	
QA Program Reviewer or Approving Official	Mike Cirian (EPA)	**Date of Review**	

Documents to Review:

1. QAPP written by Grantee or EPA must also include for review:
   Work Plan(WP) / Statement of Work (SOW) / Program Plan (PP) / Research Proposal (RP)

2. QAPP written by Contractor must also include for review:
   a) Copy of signed QARF for Task Order
   b) Copy of Task Order SOW
   c) Made available hard or electronic copy of approved QMP
   d) If QMP not approved, provide Contract SOW

3. For a Field Sampling Plan (FSP) or Sampling & Analyses Plan (SAP), the Project QAPP must also be provided.
   OR
   The FSP or SAP must be clearly identified as a stand-alone QA document and must contain all QAPP required elements (Project Management, Data Generation/Acquisition, Assessment and Oversight, and Data Validation and Usability).

Documents Submitted for QAPP Review:

1. QA Document(s) submitted for review:

QA Document	Document Date	Document Stand-alone	Document with QAPP
QAPP		Yes / No	
FSP		Yes / No	Yes / No
SAP		**Yes / No**	**Yes** / No
SOP(s)			**Yes** / No

2. WP/SOW/TO/PP/RP Date _____
WP/SOW/TO/RP Performance Period _____

3. QA document consistent with the:
WP/SOW/PP for grants? Yes / No
SOW/TO for contracts? Yes / No

4. QARF signed by R8 QAM Yes / No / NA
Funding Mechanism IA / contract / grant / NA
Amount _____

Summary of Comments *(highlight significant concerns/issues)*:

1. The individuals responsible for various activities need to be identified and contact information provided.
2. Prior to commencement of field work, a field planning meeting should be held to discuss the sampling events, communications, data management, etc.

3.
4. **The** Click here and type Entity **must address the comments in the Summary of Comments, as well as those identified in the Comment section(s) that includes a "Response (date)" and Resolved (date)".**

Element	Acceptable *Yes/No/NA*	Page/ Section	Comments
A. Project Management			
A1. Title and Approval Sheet			
a. Contains project title	No	NA	Title and Approval Sheet not provided.
b. Date and revision number line (for when needed)	No	NA	Title and Approval Sheet not provided.
c. Indicates organization=s name	No	NA	Title and Approval Sheet not provided.
d. Date and signature line for organization=s project manager	No	NA	Title and Approval Sheet not provided.
e. Date and signature line for organization=s QA manager	No	NA	Title and Approval Sheet not provided.
f. Other date and signatures lines, as needed	No	NA	Title and Approval Sheet not provided.
A2. Table of Contents			
a. Lists QA Project Plan information sections	Yes	i-iii/TOC	
b. Document control information indicated	No	NA	Document control information not indicated.
A3. Distribution List			
Includes all individuals who are to receive a copy of the QA Project Plan and identifies their organization	No	26/6.1	Distribution list was provided, however is incomplete. The distribution list needs to name the individuals to receive the plan and determine and include other individuals from EPA, DEQ, and other entities to receive the plan.
A4. Project/Task Organization			
a. Identifies key individuals involved in all major aspects of the project, including contractors	No	26/6.2	Organization chart shown on Figure 10, not Figure 11 as stated in text. Organization chart does not show the individuals responsible and affiliation.
b. Discusses their responsibilities	No	26-28/6.2	Responsibilities discussed, but individuals not specified.
c. Project QA Manager position indicates independence from unit generating data	No	27/6.2 and Figure 10	Independence of QA Manager not depicted.
d. Identifies individual responsible for maintaining the official, approved QA Project Plan	No	26/6.2	The responsibilities of the RI/FS Manager could be modified to designate this individual for maintaining the official, approved QAPP
e. Organizational chart shows lines of authority and reporting responsibilities	Yes	Figure 10	Figure requires modification based on other comments.
A5. Problem Definition/Background			

a. States decision(s) to be made, actions to be taken, or outcomes expected from the information to be obtained	Yes	28-29/6.3	
b. Clearly explains the reason (site background or historical context) for initiating this project	Yes	28-29/6.3	
c. Identifies regulatory information, applicable criteria, action limits, etc. necessary to the project	No	28-29/6.3	Regulatory information, applicable criteria, action limits, etc. necessary to the project are TBD.
A6. Project/Task Description			
a. Summarizes work to be performed, for example, measurements to be made, data files to be obtained, etc., that support the project=s goals	Yes	30/6.4	
b. Provides work schedule indicating critical project points, e.g., start and completion dates for activities such as sampling, analysis, data or file reviews, and assessments	No	30/6.4	It is understandable at this point that an exact schedule can't be defined at this time. It is suggested that general timeframes to complete each task be provided QAPP and the project schedule, when known, be provided to EPA separately.
c. Details geographical locations to be studied, including maps where possible	Yes	Figures 1-9	
d. Discusses resource and time constraints, if applicable	NA	---	If resource and time constraints exist, these should be discussed.
A7. Quality Objectives and Criteria			
a. Identifies - performance/measurement criteria for all information to be collected and acceptance criteria for information obtained from previous studies, - including project action limits and laboratory detection limits and - range of anticipated concentrations of each parameter of interest	Yes	38/6.5.6	
b. Discusses precision	Yes	39/6.5.6.1	
c. Addresses bias	Yes	39/6.5.6.2	
d. Discusses representativeness	Yes	41/6.5.6.5	
e. Identifies the need for completeness	Yes	40/6.5.6.4	
f. Describes the need for comparability	Yes	42/6.5.6.6	
g. Discusses desired method sensitivity	Yes	40/6.5.6.3	
A8. Special Training/Certifications			
a. Identifies any project personnel specialized training or certifications	Yes	43/6.6	
b. Discusses how this training will be provided	Yes	43/6.6	

c. Indicates personnel responsible for assuring training/certifications are satisfied	Yes	43/6.6	
d. identifies where this information is documented	Yes	43/6.6	
A9. Documentation and Records			
a. Identifies report format and summarizes all data report package information	No	44/6.7	Does not discuss data report package information.
b. Lists all other project documents, records, and electronic files that will be produced	No	44/6.7	Only field documentation was discussed. Other documents, for example the RI Summary Report mention elsewhere, should be included in this section.
c. Identifies where project information should be kept and for how long	No	44/6.7	Suggest providing an initial proposal and follow up with EPA.
d. Discusses back up plans for records stored electronically	No	44/6.7	This is touched upon for data in Section 7.10, however, a plan for project records is needed.
e. States how individuals identified in A3 will receive the most current copy of the approved QA Project Plan, identifying the individual responsible for this	No	44/6.7	Statements regarding how individuals will receive the most recent version of the QAPP and identifying the individual responsible for this is needed.
B. Data Generation/Acquisition			
B1. Sampling Process Design (Experimental Design)			
a. Describes and justifies design strategy, indicating size of the area, volume, or time period to be represented by a sample	Yes	7/4.1	
b. Details the type and total number of sample types/matrix or test runs/trials expected and needed	Yes	11-22/4.5-4.10	
c. Indicates where samples should be taken, how sites will be identified/located	Yes	11-22/4.5-4.10	
d. Discusses what to do if sampling sites become inaccessible	No	7/4.0	Briefly discuss the process for documenting/reporting if sites become inaccessible.
e. Identifies project activity schedules such as each sampling event, times samples should be sent to the laboratory, etc.	No	7/4.0	It is suggested that general timeframes to complete each task be provided QAPP and the project schedule, when known, be provided to EPA separately.
f. Specifies what information is critical and what is for informational purposes only	No	7/4.0	Briefly discuss what information is critical and what is for informational purposes only.
g. Identifies sources of variability and how this variability should be reconciled with project information	Yes	38/6.5.6	
B2. Sampling Methods			

a. Identifies all sampling SOPs by number, date, and regulatory citation, indicating sampling options or modifications to be taken	Yes	23/5.1	
b. Indicates how each sample/matrix type should be collected	Yes	11-22/4.5-4.10	
c. If in situ monitoring, indicates how instruments should be deployed and operated to avoid contamination and ensure maintenance of proper data	Yes	14/4.6.1	
d. If continuous monitoring, indicates averaging time and how instruments should store and maintain raw data, or data averages	NA	---	Does not appear to be any continuous monitoring.
e. Indicates how samples are to be homogenized, composited, split, or filtered, if needed	Yes	20-21/4.8-4.9	
f. Indicates what sample containers and sample volumes should be used	Yes	10-25/4.0-5.0	
g. Identifies whether samples should be preserved and indicates methods that should be followed	Yes	10-25/4.0-5.0	
h. Indicates whether sampling equipment and samplers should be cleaned and/or decontaminated, identifying how this should be done and by-products disposed of	Yes	10-25/4.0-5.0	
i. Identifies any equipment and support facilities needed	Yes	10-25/4.0-5.0	
j. Addresses actions to be taken when problems occur, identifying individual(s) responsible for corrective action and how this should be documented	No		Actions that laboratories must take when problems occur are fairly well described; however, problems in other circumstances are largely unaddressed.
B3. Sample Handling and Custody			
a. States maximum holding times allowed from sample collection to extraction and/or analysis for each sample type and, for in-situ or continuous monitoring, the maximum time before retrieval of information	Yes	Table 4	
b. Identifies how samples or information should be physically handled, transported, and then received and held in the laboratory or office (including temperature upon receipt)	Yes	46/7.3	
c. Indicates how sample or information handling and custody information should be documented, such as in field notebooks and forms, identifying individual responsible	Yes	48/7.3.3.1	

d. Discusses system for identifying samples, for example, numbering system, sample tags and labels, and attaches forms to the plan	Yes	24/5.2	
e. Identifies chain-of-custody procedures and includes form to track custody	No	---	The chain-of-custody procedures are described; however, an example form for tracking custody was not included.
B4. Analytical Methods			
a. Identifies all analytical SOPs (field, laboratory and/or office) that should be followed by number, date, and regulatory citation, indicating options or modifications to be taken, such as sub-sampling and extraction procedures	Yes	Tables 5-10	
b. Identifies equipment or instrumentation needed	Yes	Tables 5-10	
c. Specifies any specific method performance criteria	Yes	Tables 5-10	
d. Identifies procedures to follow when failures occur, identifying individual responsible for corrective action and appropriate documentation	Yes	53/7.5.2	
e. Identifies sample disposal procedures	Yes	46/5.3	
f. Specifies laboratory turnaround times needed	Yes	Tables 5-10	
g. Provides method validation information and SOPs for nonstandard methods	Yes	10/4.6.1 and SOP 5.9	The only nonstandard method appears to be XRF.
B5. Quality Control			
a. For each type of sampling, analysis, or measurement technique, identifies QC activities which should be used, for example, blanks, spikes, duplicates, etc., and at what frequency	Yes	51/7.5	
b. Details what should be done when control limits are exceeded, and how effectiveness of control actions will be determined and documented	Yes	Table 3	
c. Identifies procedures and formulas for calculating applicable QC statistics, for example, for precision, bias, outliers and missing data	Yes	36/6.5.5	
B6. Instrument/Equipment Testing, Inspection, and Maintenance			

a. Identifies field and laboratory equipment needing periodic maintenance, and the schedule for this	Yes	56/7.6 and Table 6	
b. Identifies testing criteria	Yes	56/7.6 and Table 6	
c. Notes availability and location of spare parts	Yes	56/7.6 and Table 6	
d. Indicates procedures in place for inspecting equipment before usage	Yes	56/7.6 and Table 6	
e. Identifies individual(s) responsible for testing, inspection and maintenance	Yes	56/7.6 and Table 6	
f. Indicates how deficiencies found should be resolved, re-inspections performed, and effectiveness of corrective action determined and documented	Yes	56/7.6 and Table 6	
B7. Instrument/Equipment Calibration and Frequency			
a. Identifies equipment, tools, and instruments that should be calibrated and the frequency for this calibration	Yes	57/7.7	
b. Describes how calibrations should be performed and documented, indicating test criteria and standards or certified equipment	Yes	57/7.7	
c. Identifies how deficiencies should be resolved and documented	No	57/7.7	Documenting and resolving deficiencies should be described.
B8. Inspection/Acceptance for Supplies and Consumables			
a. Identifies critical supplies and consumables for field and laboratory, noting supply source, acceptance criteria, and procedures for tracking, storing and retrieving these materials	Yes	58/7.8	
b. Identifies the individual(s) responsible for this	No	58/7.8	Identify individuals responsible.
B9. Use of Existing Data (Non-direct Measurements)			
a. Identifies data sources, for example, computer databases or literature files, or models that should be accessed and used	Yes	58/7.8	

b. Describes the intended use of this information and the rationale for their selection, i.e., its relevance to project	Yes	58/7.8	
c. Indicates the acceptance criteria for these data sources and/or models	Yes	58/7.8	
d. Identifies key resources/support facilities needed	NA	---	Not applicable.
e. Describes how limits to validity and operating conditions should be determined, for example, internal checks of the program and Beta testing	NA	---	Not applicable.
B10. Data Management			
a. Describes data management scheme from field to final use and storage	Yes	59/7.10	
b. Discusses standard record-keeping and tracking practices, and the document control system or cites other written documentation such as SOPs	Yes	59/7.10	Improvements may be need to coordinate with EPA.
c. Identifies data handling equipment/procedures that should be used to process, compile, analyze, and transmit data reliably and accurately	No	59/7.10	A process for EPA and its contractors to access the data generated needs to be developed.
d. Identifies individual(s) responsible for this	No	59/7.10	Individuals need to be identified.
e. Describes the process for data archival and retrieval	No	59/7.10	This process needs to be developed.
f. Describes procedures to demonstrate acceptability of hardware and software configurations	No	59/7.10	Procedures need to be developed.
g. Attaches checklists and forms that should be used	No	59/7.10	Checklists should be developed.
C. Assessment and Oversight			
C1. Assessments and Response Actions			
a. Lists the number, frequency, and type of assessment activities that should be conducted, with the approximate dates	Yes	62/8.1	
b. Identifies individual(s) responsible for conducting assessments, indicating their authority to issue stop work orders, and any other possible participants in the assessment process	No	62/8.1	Individuals need to be identified.
c. Describes how and to whom assessment information should be reported	No	62/8.1	Individuals need to be identified.
d. Identifies how corrective actions should be addressed and by whom, and how they should be verified and documented	No	62/8.1	Corrective action process needs to be discussed in more detail.

C2. Reports to Management			
a. Identifies what project QA status reports are needed and how frequently	No	62/8.2	
b. Identifies who should write these reports and who should receive this information	No	62/8.2	
D. Data Validation and Usability			
D1. Data Review, Verification, and Validation			
Describes criteria that should be used for accepting, rejecting, or qualifying project data	Yes	63/9.1	Criteria will be defined as project progresses.
D2. Verification and Validation Methods			
a. Describes process for data verification and validation, providing SOPs and indicating what data validation software should be used, if any	Yes	63/9.2	
b. Identifies who is responsible for verifying and validating different components of the project data/information, for example, chain-of-custody forms, receipt logs, calibration information, etc.	No	63/9.2	Individuals need to be identified.
c. Identifies issue resolution process, and method and individual responsible for conveying these results to data users	No	63/9.2	Resolution process and individuals need to be identified.
d. Attaches checklists, forms, and calculations	No	63/9.2	No checklists attached.
D3. Reconciliation with User Requirements			
a. Describes procedures to evaluate the uncertainty of the validated data	Yes	65/9.3	
b. Describes how limitations on data use should be reported to the data users	Yes	65/9.3	